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Official Title: Effect of Postoperative Oral Rinsing on Thirst-Related Discomfort, Comfort Level, and Bowel Movement in Individuals Undergoing Abdominal Surgery: A Randomized Controlled Trial

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Study Design

This study was conducted as a randomized controlled trial with pre-test and post-test design, involving intervention and control groups.

Study Setting and Duration

The research was carried out at the Department of General Surgery, Sivas Cumhuriyet University Research and Training Hospital, between June 5 2024, and December 5, 2024.

Study Population and Sample

The study population included patients who underwent abdominal surgery in the general surgery clinic during the study period. The sample size was calculated using G*Power 3.1.9.7 software by a biostatistics expert. With an effect size of 0.50, α=0.05, and power=0.85 (β=0.15), the required sample size was determined to be 82 patients (41 in the intervention group and 41 in the control group). The actual study was completed with 98 patients (49 per group), considering potential data loss. Eligible patients were stratified based on diagnosis and randomized using block randomization with a random number table in a 1:1 allocation ratio.

Inclusion and Exclusion Criteria

The study included patients who were able to communicate, aged 18 or older, agreed to participate, and were scheduled for elective surgery.

Patients were excluded if they were over 80 years old, had a mental disorder that prevented them from rinsing their mouth, were unconscious after surgery, were at risk of swallowing water during rinsing, and underwent emergency surgery.

Patients who refused to complete the post-test and those requiring intensive care after surgery were excluded.

Data Collection Tools

Four tools were used:

1. Mini Mental State Assessment Test: The Mini Mental State Assessment (MMSA) is a common screening tool to systematically and comprehensively assess individuals' cognitive status. The test consists of 11 items assessing five cognitive domains: orientation, registration, attention and calculation, recall, and language. The maximum score that can be obtained from the scale is 30, and scores of 23 or below suggest cognitive impairment. The administration time, approximately 5–10 minutes, makes the tool suitable for routine use in clinical and research settings. Its validity and reliability in Turkish were conducted.

2. Personal Information Form: The questionnaire, which included the participants' descriptive and clinical characteristics, was developed by the researchers in two sections based on literature and clinical observations. The first section consisted of seven questions covering the patient's descriptive characteristics, including age, gender, and education level, in line with the study group, and the patient's clinical characteristics, including diagnosis, preoperative fasting time, postoperative oral intake time, and the time to start oral intake. The second section included a chart created for recording bowel sounds.

3. Surgical Period Thirst Discomfort Scale (SPTDS): The original seven-item scale was removed due to the low factor analysis of one item in the Turkish validity and reliability study. It was adapted as six items using a three-item Likert-type scale. Ratings are as follows: “Didn't Bother (0),” “A Little Bit Bothered (1), and “A Lot Bothered (2). The scale items are: “My Mouth is Dry,” “My Lips are Dry,” “My Saliva is Thick,” “My Throat is Dry,” “I Have a Bad Taste in My Mouth,” and “I Want to Drink Water.” The minimum score for the total scale is 0, and the maximum score is 12. As the score obtained from the scale increases, the level of discomfort related to thirst also increases.

4. Comfort Level Determination Scale - VAS: The comfort level of the individuals participating in the study will be determined using the Visual Analog Scale-10 (VAS-10). The scale is a 10-cm straight line with points spaced 1 cm apart. Each point on this straight line will be evaluated as a score for the comfort level, with the starting point being "0 = Lowest Comfort Level" and "10 = Highest Comfort Level." As the score obtained from the scale increases, the comfort level also increases.

Intervention Procedure

Before initiating the main study, a pilot application was conducted with a total of eight patients—four from the experimental group and four from the control group—to evaluate the data collection instruments and the implementation process. The results of the pilot study indicated that all scale items were found to be clear and understandable by the participants, and the average response time ranged between 10 and 12 minutes. No technical or logistical problems were encountered during the process, and the main study was subsequently initiated. Data obtained from the pilot study were not included in the main sample.

During the pilot phase, data collection instruments were administered to the experimental group patients after each oral rinse. However, as patients provided near-perfect responses across all measurements, a potential risk of bias was identified. Therefore, in the main study, the data collection instruments were administered only before the first oral rinse and after the completion of all three rinses.

The purpose of the study was explained to all participants, and written informed consent was obtained. Data were collected face-to-face by the researchers.

In the experimental group, postoperative cognitive assessment was conducted, and patients scoring 23 or higher on the MMSE (Mini-Mental State Examination) were instructed to perform oral rinsing three times at 20-minute intervals, each time using 20 ml of distilled water. Two graduated plastic cups were used for each rinsing: one containing 20 ml of distilled water and one empty cup for spitting out the rinse water. This setup enabled the evaluation of whether patients swallowed the water; none of the patients did, and all participated in the procedure compliantly. Data collection forms were administered face-to-face before the first rinse and 15 minutes after the final rinse, and bowel sounds were auscultated.

In the control group, postoperative cognitive assessment was also conducted, and patients scoring 23 or higher on the MMSE were administered the data collection forms and had their bowel sounds auscultated. No intervention was applied to this group. The data collection forms were re-administered 75 minutes later, in a manner consistent with the experimental group, and bowel sounds were re-evaluated.

To ensure consistency and avoid inter- or intra-group differences, all bowel sound assessments were performed using the same brand and model of stethoscope, and each patient's bowel sounds were auscultated for one minute. Considering the oral rinsing process, the total time required for data collection in the experimental group was approximately 20–25 minutes.

Data Analysis

SPSS 22.00 package program was used to analyze the data. Skewnes-Kurtosis analyses were performed to determine the conformity of the data to a normal distribution. A Skewnes-Kurtosis value between +1.96 and -1.96 is considered a normal distribution. All data used in the study were within the normal range, and the data showed a normal distribution. Frequency (n) and percentage (%) distributions were calculated to determine the sociodemographic and clinical characteristics of the participants. A t-test for independent samples was used to determine the mean differences between two independent groups, a t-test for dependent samples was used to compare pre- and post-intervention measurements, and a single-factor analysis of variance (ANOVA) was used for repeated measures. Cohen's d effect size was calculated to assess the significance of the difference between the groups in terms of the intervention. Statistical significance was accepted as $p<0.05$.

RESULTS

The mean age of the participants in the experimental group was 56.41±14.80 years, while in the control group it was 55.78±14.00 years. Overall, 57.1% of the participants were female. Among the patients, 46.9% of those in the experimental group and 42.9% in the control group were primary school graduates.

Clinically, 49% of the patients underwent surgery for cholecystectomy. The preoperative fasting period ranged between 7–18 hours in the experimental group, with a mean of 11.78±2.47 hours, and between 8–36 hours in the control group, with a mean of 12.78±4.33 hours.

The postoperative oral intake initiation time in the experimental group ranged between 6–20 hours, with a mean of 10.41±4.64 hours, while in the control group it ranged between 2–66 hours, with a mean of 15.20±11.57 hours. The

difference between the two groups was statistically significant (t=-2.635, p=0.010), indicating that patients in the experimental group began oral intake earlier than those in the control group. All patients in the experimental group started oral intake within 6–24 hours, whereas 88% of the control group started within 6–24 hours, 8% between 24–48 hours, and 4% after more than 48 hours. This difference was also statistically significant (χ^2=6.391, p=0.041), again showing that oral intake began earlier in the experimental group.

Before mouth rinsing, the mean VAS Comfort Level score in the experimental group was 3.59±1.29, the mean Surgical Thirst Discomfort Scale (SPTDS) score was 8.00±2.84, and the mean number of bowel sounds was 3.49±1.06. In the control group, the initial mean VAS Comfort Level score was 4.02±1.71, the mean SPTDS score was 8.14±2.74, and the mean number of bowel sounds was 4.06±1.52. No significant differences were found between the groups in terms of VAS Comfort Level (t=1.399, p=0.165) or SPTDS (t=-0.253, p=0.801), indicating similar baseline comfort and thirst discomfort levels. However, the difference in bowel sound frequency was significant (p<0.05), favoring the control group, with a moderate effect size (Cohen's d=0.44).

After oral rinsing, the mean VAS Comfort Level score in the experimental group increased to 7.33±1.14, while in the control group's second measurement it was 3.86±0.94. This difference was statistically significant (t=16.438, p<0.001), demonstrating that oral rinsing significantly improved comfort, with a very large effect size (Cohen's d=3.32).

The mean SPTDS score decreased to 1.31±1.54 in the experimental group after oral rinsing, compared to 8.59±2.15 in the control group's second measurement. The difference was statistically significant (t=-19.269, p<0.001), indicating that oral rinsing significantly reduced thirst-related discomfort, with a very large effect size (Cohen's d=3.89).

The mean number of bowel sounds increased to 5.98±1.61 in the experimental group after oral rinsing, whereas it was 3.86±1.22 in the control group's second measurement. This difference was statistically significant (t=7.334, p<0.001), suggesting that oral rinsing enhanced bowel motility, with a large effect size (Cohen's d=1.48).

Within-group comparisons showed that in the experimental group, post-rinsing measurements demonstrated an increase in comfort level, a decrease in thirst-related discomfort, and an increase in bowel motility compared to pre-rinsing values. In contrast, no significant changes were observed between the two measurements in the control group.

These findings indicate that oral rinsing led to significant improvements in comfort, reduction of thirst-related discomfort, and stimulation of bowel motility in the experimental group, while no meaningful changes occurred in the control group.

CONCLUSION

In conclusion, oral rinsing with plain water is an effective, cost-free, and easily applicable method for reducing postoperative thirst discomfort, enhancing comfort, and accelerating bowel movements. It is recommended that this practice be integrated into routine care in surgical clinics.

INFORMED CONSENT FORM

Dear Participant,

You are invited to participate in a scientific research study entitled: "The Effect of Postoperative Oral Rinsing on Thirst-Related Discomfort, Comfort Level, and Bowel Motility in Patients Undergoing Abdominal Surgery Under General Anesthesia: A Randomized Controlled Trial."

The aim of this study is to examine the experience of thirst in patients undergoing abdominal surgery under general anesthesia and to evaluate the effect of oral rinsing on thirst.

Participation in this study is entirely voluntary. Before you make your decision, we would like to provide you with information about the research. If, after reading and understanding this information, you agree to participate, please sign this form.

During the study, you will be asked to complete certain questionnaires before and after surgery to assess your level of thirst. Since you are in the intervention group, you will be asked to rinse your mouth with 30 ml of water after surgery. Researchers will periodically collect your responses using questionnaire forms and will listen to and record your bowel sounds. It is sufficient for you to be hospitalized during the surgical process—no additional hospital visits will be required for this study.

As part of your participation, you are expected to undergo standard hospital procedures and to respond to the researcher's questions accurately and honestly. There is no anticipated risk or harm to you from participating in this study. The potential benefits include identifying your thirst status and its relationship with bowel activity. On a broader level, your participation may help prevent future problems through the development of scientific nursing practices and contribute to evidence-based patient care.

If you agree to participate, questionnaire forms will be administered before and after surgery, and your bowel sounds will be assessed and recorded by the researchers Ayşegül Kaya İmrek and Pınar Yılmaz Eker. Before surgery, you will be asked five short questions regarding your personal characteristics, such as age, gender, marital status, education level, and preoperative fasting duration. These will be recorded by the researcher.

If any development arises during the course of the research that may affect your participation, you or your legal representative will be informed immediately. For further information about the study, or if you experience any discomfort or adverse effects, you may contact Pınar Yılmaz Eker at +90 530 946 89 19.

Furthermore, all examinations, tests, and medical care related to this research will be provided free of charge. In the event that any health problem arises directly or indirectly due to the study, all necessary medical interventions will be provided without charge or use of your personal health insurance.

Participation in this study is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. The investigator may also withdraw you from the study if you do not follow the protocol, disrupt the study schedule, or for other scientific or medical reasons. The results of the study will be used for scientific purposes, and even if you withdraw, your medical data may still be used anonymously for scientific analysis, if necessary.

All your personal and medical information will be kept confidential. Even if the results are published, your identity will not be disclosed. However, authorized monitoring bodies, ethics committees, or regulatory authorities may access your medical records for study-related review. You also have the right to access your own medical information at any time.

CONSENT TO PARTICIPATE IN THE STUDY

I have read and/or listened to the information provided above regarding this research study. I have asked all my questions and received satisfactory answers. I fully understand the explanations provided to me in both written and verbal form. I have been given sufficient time to decide whether or not I wish to participate. Under these conditions, I voluntarily give my consent to participate in the study and authorize the research team to access, transfer, and process my medical data. I confirm that I am participating without any pressure or coercion.

A signed copy of this form will be given to me.

Participant Information
Full Name:
Address:
Phone/Fax:
Date & Signature:

Investigator Information

Full Name:
Title/Position:
Institution Address:
Phone/Fax:
Date & Signature:

Witness to the Consent Process (if applicable)

Full Name:
Title/Position:
Institution Address:
Phone/Fax:
Date & Signature: